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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,396	11/28/2000	James F. Young	10271-007-999	8214

20583 7590 07/28/2003

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EXAMINER

BROWN, STACY S

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 07/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,396

Applicant(s)

YOUNG ET AL.

Examiner

Stacy B Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73,74,85-94,99-110,180,181,186,187 and 189-191 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73,74,85-94, 99-110,180,181,186,187 and 189-191 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 23, 2003 has been entered. Claims 73, 74, 85-94, 99-110, 180, 181, 186, 187 and 189-191 are pending and examined.

2. The following rejections are withdrawn or moot:

- The rejection of claims 200-230 under 35 U.S.C. 112, first paragraph is moot, in view of the cancellation of claims 200-230.
- The rejection of claims 85-110 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's persuasive arguments.
- The rejection of claim 74 under 35 U.S.C. 102(b) as anticipated by Johnson *et al* (*J. Infect. Dis.*, 1997, 176:1215-1224) is withdrawn in view of Applicant's persuasive arguments. Johnson fails to teach intranasal administration of palivizumab.
- The rejection of claims 73 and 85-94 under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of Lam *et al* (*Proc. Int'l Symp. Rel. Bioact. Mater.*, 1997, 24:759-760) is withdrawn. Applicant's arguments were not persuasive. The Johnson reference is withdrawn in an attempt to simplify the rejection (see the new rejections below).

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- The rejection of claims 95-110, 180-181, 186-187 and 189-191 under 35 U.S.C. 103(a) as unpatentable over Johnson in view of MedImmune (package insert, 1999) and Lam is withdrawn or moot (with respect to cancelled claims).

Applicant's arguments were not persuasive. The Johnson reference is withdrawn in an attempt to simplify the rejection (see the new rejections below).

Claim Objections

3. Claims 89, 91 and 187 are objected to because "intravenously" is misspelled.

Claim Rejections - 35 USC § 112

4. Claim 187 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 187 recites that palivizumab is administered intramuscularly, intravenously or subcutaneously. However, claim 187 depend from either of claims 180-181, which recite that palivizumab is administered to the lungs. The claim language in claim 181 suggests that the administration of palivizumab is more direct than intramuscular, intravenous or subcutaneous administration. Clarification is requested.

Claim Rejections - 35 USC § 103

5. Claims 73, 85, 86, 89, 90, 91, 92, 99, 100 and 103-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over MedImmune, Inc. (SYNAGIS® package insert) in view of

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Lam *et al* (*Proc. Int'l Symp. Rel. Bioact. Mater.*, 1997, 24:759-760), both of record. Applicant's arguments have been carefully considered but fail to persuade.

Applicant mainly argues that one would not have had a reasonable expectation of success that Lam's method of sustained release formulation would work with Applicant's antibody because Lam's anti-VEGF Fab fragment is expected to have a different pharmacokinetic profile than Applicant's antibody. In response, Applicant's claims are drawn to *fragments* of palivizumab that immunospecifically bind to an antigen. Lacking evidence to the contrary, one would have a reasonable expectation of success that Fab fragments from monoclonal antibodies would be successfully formulated into Lam's sustained release composition.

6. Claims 74, 87, 88, 93, 94, 101, 102, 107-110, 180, 181, 186, 187, 189, 190 and 191 are rejected under 35 U.S.C. 103(a) as being unpatentable over MedImmune, Inc. (SYNAGIS® package insert) in view of Lam *et al* (*Proc. Int'l Symp. Rel. Bioact. Mater.*, 1997, 24:759-760) as applied to claims 73, 85, 86, 89, 90, 91, 92, 99, 100 and 103-106 above, and further in view of Gonzalez *et al* (6,117,980).

The claims are drawn to compositions of palivizumab for pulmonary delivery and methods of administering sustained release palivizumab via pulmonary delivery. The teachings of MedImmune and Lam are of record. MedImmune fails to teach the pulmonary delivery of their humanized monoclonal antibody.

However, Gonzalez teaches the administration of a humanized anti-IL-8 monoclonal antibody or fragments thereof via known therapeutic formulation methods, such as inhalation, injection, intramuscular and sustained release. The antibody is administered systemically or at a

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site of inflammation (col. 60, lines 53-60). One would have been motivated to use a method of inhalation to administer palivizumab to the lungs because Gonzalez teaches known methods of preparing humanized antibodies or fragments thereof. Given that the lungs are primarily affected by RSV infection, one would have been motivated to administer palivizumab closer to the site of infection, as suggested by Gonzalez (col. 60, lines 59-60). One would have had a reasonable expectation of success that the palivizumab would work in a therapeutic formulation for inhalation because Gonzalez administers a humanized antibody and fragments thereof by inhalation. With regard to the specific amounts of palivizumab in the body after 20 days, one of ordinary skill in the art would have been able to optimize the sustained release formulation to maintain the necessary concentration of antibody for effective therapy.

Conclusion

7. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SBC 7/24/03
Stacy B. Chen

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